General

Guideline Title

Cervical cerclage.

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). Cervical cerclage. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 May. 21 p. (Green-top guideline; no. 60). [64 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Classification of evidence levels (1++ to 4) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

History-Indicated Cerclage

When Should a History-Indicated Cerclage Be Offered?

B - History-indicated cerclage should be offered to women with three or more previous preterm births and/or second-trimester losses.

B - History-indicated cerclage should not be routinely offered to women with two or fewer previous preterm births and/or second-trimester losses.

Ultrasound-Indicated Cerclage

When Should an Ultrasound-Indicated Cerclage Be Offered?

Women with a Singleton Pregnancy and No History of Spontaneous Mid-trimester Loss or Preterm Birth

B - The insertion of an ultrasound-indicated cerclage is not recommended in women without a history of spontaneous preterm delivery or second-trimester loss who have an incidentally identified short cervix of 25 mm or less.

Women with a Singleton Pregnancy and a History of Spontaneous Mid-trimester Loss or Preterm Birth

A - Women with a history of one or more spontaneous mid-trimester losses or preterm births who are undergoing transvaginal sonographic surveillance of cervical length should be offered an ultrasound-indicated cerclage if the cervix is 25 mm or less and before 24 weeks of gestation.

C - An ultrasound-indicated cerclage is not recommended for funnelling of the cervix (dilatation of the internal os on ultrasound) in the absence of cervical shortening to 25 mm or less.

Who Should Be Offered Serial Sonographic Surveillance ± Ultrasound-Indicated Cerclage?

B - Women with a history of spontaneous second-trimester loss or preterm delivery who have not undergone a history-indicated cerclage may be offered serial sonographic surveillance, as there is evidence to suggest that those who experience cervical shortening are at an increased risk of subsequent second trimester loss/preterm birth and may benefit from ultrasound-indicated cerclage, while those whose cervix remains long have a low risk of second-trimester loss/premature delivery.

D - Women should be informed that expectant management is a reasonable alternative since there is a lack of direct evidence to support serial sonographic surveillance over expectant management. Furthermore, the majority of women with a history of second-trimester loss/preterm delivery will deliver after 33 weeks of gestation.

Can Cervical Cerclage Be Recommended in Any Other Groups Considered at Increased Risk of Spontaneous Preterm Delivery?

Multiple Pregnancies

B - The insertion of a history- or ultrasound-indicated cerclage in women with multiple pregnancies is not recommended, as there is some evidence to suggest it may be detrimental and associated with an increase in preterm delivery and pregnancy loss.

Uterine Anomalies and Cervical Trauma

B - History- or ultrasound-indicated cerclage cannot be recommended in other high-risk groups such as women with müllerian anomalies, previous cervical surgery (cone biopsy, large loop excision of the transformation zone or destructive procedures such as laser ablation or diathermy) or multiple dilatation and evacuation.

Transabdominal Cerclage

When Should a Transabdominal Cerclage Be Considered?

D - In women with a previous failed transvaginal cerclage, insertion of a transabdominal cerclage may be considered, but this procedure may be associated with increased maternal morbidity.

Should an Abdominal Cerclage Be Performed Laparoscopically?

D - There is no evidence to support a laparoscopic approach over laparotomy in the insertion of an abdominal cerclage.

How Should a Delayed Miscarriage or Fetal Death Be Managed in Women with an Abdominal Cerclage?

D - Successful evacuation through the stitch by suction curettage or by dilatation and evacuation (up to 18 weeks of gestation) has been described; alternatively, the suture may be cut, usually via a posterior colpotomy. Failing this, a hysterotomy may be required or caesarean section may be necessary.

Rescue Cerclage

When Should a Rescue Cerclage Be Considered?

D - The decision to place a rescue suture should be individualised, taking into account the gestation at presentation, as even with rescue cerclage the risks of severe preterm delivery and neonatal mortality and morbidity remain high. A senior obstetrician should be involved in making the decision.

B - Insertion of a rescue cerclage may delay delivery by a further 5 weeks on average compared with expectant management/bed rest alone. It may also be associated with a two-fold reduction in the chance of delivery before 34 weeks of gestation. However, there are only limited data to support an associated improvement in neonatal mortality or morbidity.

D - Advanced dilatation of the cervix (more than 4 cm) or membrane prolapse beyond the external os appears to be associated with a high chance of cerclage failure.

There is no clear evidence that the gestation at which the cerclage is inserted affects the magnitude of prolongation in gestation; however, consideration should be given to the fact that, in cases presenting before 20 weeks of gestation, insertion of a rescue cerclage is highly likely to result in a preterm delivery before 28 weeks of gestation. Furthermore, the decision to place a rescue cerclage beyond 24 weeks of gestation should be individualised and take into account the local gestational age of viability. Improvements in neonatal intensive care have advanced the gestational age of viability to 24 weeks of gestation in most developed countries and, given the potential risk of iatrogenic membrane rupture and subsequent preterm delivery, rescue cerclage can rarely be justified after this gestation. [Evidence level 4]

What Information Should Be Given to Women Before Cerclage Insertion?

Before history- or ultrasound-indicated cerclage insertion, a woman should be given information about the potential complications, which should include the following:

B - Cerclage insertion is associated with a doubling in risk of maternal pyrexia but no apparent increase in chorioamnionitis.

B - Cerclage insertion is not associated with an increased risk of preterm prelabour rupture of membranes (PPROM), induction of labour or caesarean section.

B - The insertion of a cervical suture is not associated with an increased risk of preterm delivery or second-trimester loss.

Before any type of cerclage insertion, women should be informed of the following:

D - There is a small risk of intraoperative bladder damage, cervical trauma, membrane rupture and bleeding during insertion of cervical cerclage.

D - Cervical cerclage may be associated with a risk of cervical laceration/trauma if there is spontaneous labour with the suture in place.

Preoperative Management

Should Amniocentesis to Detect Infection Be Performed Before Rescue or Ultrasound-Indicated Cerclage?

D - In selected cases where there is suspicion of intra-amniotic infection, amniocentesis may be performed to aid the decision about rescue cerclage, as the presence of infection is associated with a poor prognosis.

D - Amniocentesis before rescue cerclage does not appear to increase the risk of preterm delivery before 28 weeks of gestation.

Is Amnioreduction Before Rescue Cerclage Recommended?

D - There is an absence of data to either refute or support the use of amnioreduction before insertion of a rescue cerclage.

Operative Issues

Should Perioperative Tocolysis Be Used for Insertion of Cerclage?

D - There is no evidence to support the use of routine perioperative tocolysis in women undergoing insertion of cerclage.

Can Cerclage Be Performed as a Day-Case Procedure?

C - Elective transvaginal cerclage can safely be performed as a day-case procedure.

Which Technique and Material Should Be Used?

D - The choice of transvaginal cerclage technique (Shirodkar versus McDonald) should be at the discretion of the surgeon.

C - There is no current evidence to support the placement of two purse-string sutures over a single suture.

Adjuvant Management

Is There a Role for Post-Cerclage Serial Sonographic Surveillance of Cervical Length?

D - While routine serial sonographic measurement of the cervix is not recommended, it may be useful in individual cases following ultrasound-indicated cerclage to offer timely administration of steroids or in utero transfer.

Is There a Role for Repeat Cerclage When Cervical Shortening Is Seen Post-Cerclage?

D - Placement of an ultrasound-indicated cerclage in the presence of cervical length shortening cannot be recommended as, compared with

expectant management, it may be associated with an increase in both pregnancy loss and delivery before 35 weeks of gestation.

Is Fetal Fibronectin Testing Useful Following Insertion of a Cervical Cerclage?

C - Routine fetal fibronectin testing is not recommended post-cerclage. However, the high negative predictive value of fetal fibronectin testing for subsequent delivery at less than 30 weeks of gestation in asymptomatic high-risk women with a cerclage in place may provide reassurance to women and clinicians in individual cases. However, the increased false-positive rate of fetal fibronectin testing in such women makes the finding of a positive result less useful.

When Should the Cerclage Be Removed?

Should the Cerclage Be Removed following PPROM?

D - In women with PPROM between 24 and 34 weeks of gestation and without evidence of infection or preterm labour, delayed removal of the cerclage for 48 hours can be considered, as it may result in sufficient latency that a course of prophylactic steroids for fetal lung maturation is completed and/or in utero transfer arranged.

C - Delayed suture removal until labour ensues or delivery is indicated is associated with an increased risk of maternal/fetal sepsis and is not recommended.

Definitions:

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Cervical conditions which may lead to spontaneous preterm birth or mid-trimester pregnancy loss

Guideline Category

Counseling

Management

Prevention

Risk Assessment

Clinical Specialty

Obstetrics and Gynecology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To review the literature and provide evidence-based guidance on the use of cerclage

Target Population

Women at risk of mid-trimester loss and spontaneous preterm birth and their fetuses

Interventions and Practices Considered

1. Cervical cerclage
    - Transvaginal cerclage
    - Transabdominal cerclage
    - Rescue cerclage
2. Management of delayed miscarriage or fetal death
3. Use of serial sonographic surveillance

4. Counseling women on potential complications of cervical cerclage
5. Use of amniocentesis before rescue cerclage
6. Transvaginal cerclage technique (Shirodkar versus McDonald)
7. Transvaginal cerclage as a day-case procedure
8. Suture removal following preterm prelabour rupture of membranes

Note: The following were considered by not recommended: use of amnioreduction before rescue cerclage, use of routine perioperative tocolysis, fetal fibronectin testing following insertion of a cervical cerclage.

Major Outcomes Considered

- Incidence of pre-term delivery
- Perinatal or maternal morbidity or mortality
- Neonatal survival
- Operative complications
- Cerclage failure

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This Royal College of Obstetricians and Gynaecologists (RCOG) guideline was developed in accordance with standard methodology for producing RCOG Green-top guidelines. The Cochrane Library (including the Cochrane Database of Systematic Reviews), DARE, EMBASE, TRIP, Medline and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. The search was restricted to articles published between 1980 and November 2008. The databases were searched using the relevant MeSH terms, including all subheadings, and this was combined with a keyword search. Search words included 'cervical cerclage', 'cervical suture' 'midtrimester miscarriage', 'McDonald cerclage', 'Shirodkar cerclage', 'infection and cerclage', 'tocolytics and cerclage' and 'inflammatory mediators and cerclage', and the search was limited to humans and the English language. The National Library for Health and the National Guideline Clearinghouse were also searched for relevant guidelines and reviews.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Reviewing and Grading of Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html). An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2–) will be excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality RCTs when higher-quality observational evidence is available.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network

(SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use, technique and timing of cerclage which may reduce the chance of pre-term delivery

Potential Harms

- Cerclage insertion is associated with a doubling in risk of maternal pyrexia but no apparent increase in chorioamnionitis.
- There is a small risk of intraoperative bladder damage, cervical trauma, membrane rupture and bleeding during insertion of cervical cerclage.
- Shirodkar cerclage usually requires anaesthesia for removal and therefore carries the risk of an additional anaesthetic.
- Cervical cerclage may be associated with a risk of cervical laceration/trauma if there is spontaneous labour with the suture in place.

Contraindications

Contraindications

The contraindications to cerclage insertion are:

- Active preterm labour
- Clinical evidence of chorioamnionitis
- Continuing vaginal bleeding
- Preterm prelabour rupture of membranes (PPROM)
- Evidence of fetal compromise
- Lethal fetal defect
- Fetal death

Qualifying Statements

Qualifying Statements

- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research might be indicated.
- The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available within the appropriate health services. This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). Cervical cerclage. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 May. 21 p. (Green-top guideline; no. 60). [64 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 May

Guideline Developer(s)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

Guideline Committee

Guidelines Committee

Composition of Group That Authored the Guideline

Authors: Professor AH Shennan FRCOG, London; Ms MS To MRCOG, London

Peer Reviewers: BLISS (Babies Born too Soon, too Small, too Sick); RCOG Consumers' Forum; Royal College of Midwives; Mrs A Diyaf MRCOG, Nottingham; Ms LMM Duley FRCOG, Leeds; Mr RG Farquharson FRCOG, Liverpool; Ms SK Flint FRCOG, Tunbridge Wells; Mr KT Moriarty MRCOG, Warwickshire; Dr NC Smith FRCOG, Aberdeen

Guidelines Committee Lead Reviewers: Mr M Griffiths FRCOG, Luton; Dr K Langford FRCOG, London

Financial Disclosures/Conflicts of Interest

Conflicts of interest: none declared.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .

Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .
- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the RCOG Web site .

In addition, suggested audit topics are available in section 16 of the original guideline document .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 26, 2012.

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